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PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:
ROSCHKE *et al.*
Appl. No.: 10/067,800
Filed: February 8, 2002
For: **Human G-Protein Chemokine Receptor (CCR5) HDGNR10**

Confirmation No.: 8493
Art Unit: 1647
Examiner: Turner, Sharon L.
Atty. Docket: 1488.115000I/EKS/HCC

Reply to Restriction Requirement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

In reply to the Office Action dated November 2, 2004, requesting an election of one invention to prosecute in the above-referenced patent application, Applicants hereby provisionally elect to prosecute the invention of Group II, represented by claims 20-27, 30-50, and 59-60 (cancelled herein) and newly presented claims 61-83. Applicants further provisionally elect the 1D8 antibody produced by the XF11.1D8 hybridoma (Group (l)). This election is made without prejudice to or disclaimer of the other claims or inventions disclosed.

This election is made **with** traverse.

Preliminarily, Applicants have cancelled claims 2-60 and have submitted new claims 61-84 (see Preliminary Amendment submitted herewith). Applicants submit that new claims 61-83 are directed to subject matter encompassed by Group II as cast by the Examiner, and that new claim 84 is directed to subject matter encompassed by Group IV

as cast by the Examiner. Applicants traverse the restriction requirement, at least as it applies to Groups I, II and IV.

Applicants point out that M.P.E.P. § 803 lists the criteria for a proper restriction requirement:

> Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP § 806.04 – § 806.04(i)) or distinct (MPEP § 806.05 – § 806.05(i)).
>
> If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Thus, even assuming, *arguendo*, that Groups I, II and IV represented distinct or independent inventions, restriction remains improper unless it can be shown that the search and examination of all groups would entail a "serious burden." *See* M.P.E.P. § 803. Applicants submit that a search of the elected group of claims directed to the antibodies comprising the amino acid sequences of the VH and VL domains of the 1D8 antibody, (SEQ ID NOS:60 and 62, respectively) would clearly provide useful information for the remaining groups. For example, the search for publications which disclose antibodies comprising the amino acid sequences of the VH and VL domains of the 1D8 antibody would lead the Examiner to references which disclose polynucleotides encoding the antibodies (Group I), and methods of using antibodies comprising the amino acid sequences of the VH and VL domains of the 1D8 antibody for detecting G protein Coupled Receptor (CCR5) polypeptide. Applicants submit that it would not be a serious burden to examine all the claims of Groups I, II and IV together.

Applicants respectfully request that the present restriction requirement, at least as it applies to Groups I, II and IV, be withdrawn upon consideration of the above arguments and in view of M.P.E.P. § 803.

Election from Groups (a)-(p)

The Examiner further requested that Applicants elect a "nucleotide encoding VH or VL region of hybridoma" selected from one of Groups (a)-(p). (Paper mailed November 2, 2004, ¶ 9.) Applicants assume the Examiner's reference to "the above XVIII Groups" in paragraph 9 of the restriction requirement is an error and that the above **IV** Groups" was meant since paragraph three of the restriction requirement only defines IV Groups. As indicated above, Applicants elect Group (l), **with traverse**.

Preliminarily Applicants note that Groups (a)-(l) are hybridomas and not nucleotides encoding VH or VL regions from a hybridoma. Furthermore, Groups (m)-(p) are not hybridomas or nucleotides encoding VH or VL regions from a hybridoma. Instead, Groups (m)-(p) define regions of the CCR5 antigen. Given that Applicants have provisionally elected the antibody (protein) of Group II, Applicants submit that the requirement to elect a nucleotide is inappropriate. Further, Applicants submit that Groups (m)-(p) are improperly included in the restriction between individual hybridomas and should be excluded from further election.

Telephone conversation with the Examiner

In a telephone conversation with Applicants' representative, Michele Shannon, on November 1, 2004, the Examiner clarified that Applicants were to elect a particular hybridoma. The Examiner acknowledged that Groups (m)-(p) were not consistent with the required election but was unable to amend this language since the restriction requirement had already been mailed. The Examiner suggested that Applicants traverse the requirement as it applies to Groups (m)-(p) and argue that these groups are improperly included in the restriction between individual hybridomas. Accordingly, Applicants request that Groups (m)-(p) be withdrawn from the requirement for election.

Request for Rejoinder

The Examiner required restriction between product (Groups I and II) and process claims (Groups III and IV) (Paper mailed November 2, 2004, ¶ ¶ 8 and 17.) In accordance with the decisions in *In re Ochiai,* 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer,* 77 F.3d 422, 37 USPQ 2d 1663 (Fed. Cir. 1996), and the notice published in the Official Gazette on March 26, 1996, setting forth new guidelines for the treatment of restricted product and process claims (*see* 1184 OG 86), Applicants respectfully request that if the restriction requirement is made final and if the claims of Group II (new claims 61-83) are found allowable, that the claim of Group IV (new claim 84) be rejoined and examined for patentability. *See* also M.P.E.P. § 821.04.

Species election of claim 53

The Examiner stated that claim 51 is generic to a plurality of distinct species comprising various diseases or disorders and requested that Applicants elect a single disclosed species as disclosed in elements (a)-(r) of claim 53. (*See* Paper mailed November 2, 2004, ¶ 18.) Applicants have canceled claims 51 and 53. New claims 61-84 are not generic to a plurality of distinct species of diseases and disorders and do not contain elements (a)-(r). Thus, this election of species requirement is moot.

Summary of Record of Interview

In connection with mailing of the restriction requirement, the Examiner sent out an Interview Summary which indicated that Applicants' reply to the "last office action must include the substance of the interview. (See MPEP Section 713.04)" However, applicants note that MPEP 713.04 at 700-200 states that "[d]iscussions regarding only procedural matters . . . pointing out typographical errors . . . in Office Actions are excluded from the Interview recordation procedures below." The Interview between Beth Fowble and Examiner Turner on October 22, 2004 was simply a communication that page two of the restriction requirement as mailed on October 5, 2004 was missing which is clearly a procedural/typographical matter. Accordingly, pursuant to MPEP section 713.04, there is no need for Applicants to provide a separate interview summary. For the record, however, Applicants hereby state that the substance of the interview as set forth in the Examiner's Interview Summary is accurate.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

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Date: January 3, 2005

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